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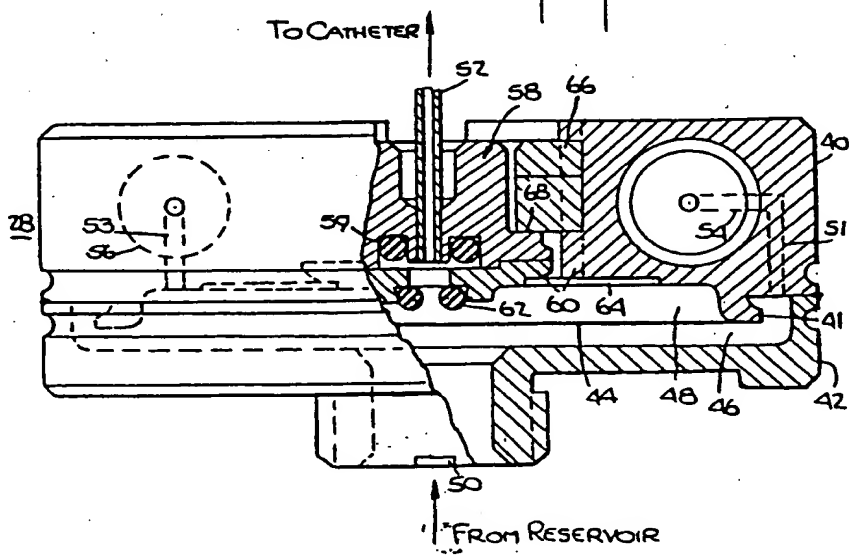
(54) Adjustable flow regulator for use in an implantable drug infusion system.

(57) A flow regulator 28 for use in an implantable drug delivery system, said regulator comprising a body 40, 42 having an internal cavity divided by a movable diaphragm 44 to define a lower section 46 and an upper section 48, an inlet 50 for receiving fluid from a pressure actuated drug delivery device 10 in said system and in fluid communication with said lower section, an outlet 52 in fluid communication with said upper section, a duct means 38 for establishing fluid communication between said lower and upper sections, and a means 66 for adjusting the flow rate to said outlet from said second section to a set, predetermined level.

Fig. 2.



EP 0 409 511 A1

ADJUSTABLE FLOW REGULATOR FOR USE IN AN IMPLANTABLE DRUG INFUSION SYSTEM

This invention is directed to an adjustable flow regulator for use in an implantable drug delivery system for accurately controlling the flow rate of a drug. This invention is an improvement which relates to a compensating mechanism for an implantable pump. This device is used to deliver drugs at a very slow rate over a long period of time between subcutaneous refills.

An implantable infusion pump of the prior art (U.S. 3,731,681) utilizes the vapor pressure of a two stage gas to maintain a constant pressure on a drug flowing through a capillary tube in order to maintain a constant flow rate. This technique of flow control while simple and reliable is sensitive to outside variables such as body temperature and atmospheric pressure.

Another implantable pump system of the prior art (U.S. 4,299,220) employs a regulator to compensate for variations in pressure and temperature to provide a more accurate and uniform rate of drug delivery. This regulator employs a body having a shallow internal cavity and a flexible diaphragm in the body which divides the cavity into two sections. An outlet from the second of the sections is centrally disposed in the wall of the cavity underlying the diaphragm. Flexing of the diaphragm in one direction contacts an elastomeric sealing ring around the outlet and closes the fluid passage-way. The inlet of the regulator body is connected to the capillary flow line from a pressure actuated drug delivery device. The flow line includes a capillary restrictor upstream from the inlet to the second section. The capillary restrictor is thus in series with the flow control valve which is formed by the outlet and the diaphragm. When the opposing forces on the diaphragm are stable, the diaphragm is stationary. If there is a change in these forces, the diaphragm deflects either to close the valve when the pressure difference is negative in the second section or to open the valve if the pressure difference is positive in the second section. One of the difficulties in this system is the ability to adjust the position of the diaphragm in relation to the valve. Consequently, the device which is generally a fixed assembly provides a widely varying initial flow rate due to manufacturing tolerances and is impossible to normalize.

It is an object of the invention to provide an implantable infusion system which can be adjusted and calibrated to insure that performance can be optimized to design specifications and patient requirements.

According to the present invention, there is provided an implantable drug delivery system comprising a pressure actuated drug delivery device having a housing, a movable bellows dividing said housing into a first chamber containing a drug to be dispensed and a second chamber containing a material exerting pressure on said bellows, means for providing access to said first chamber for refilling it with a drug, and characterized by an adjustable flow regulator connected to said first chamber, said flow regulator having an inlet from said first chamber and an outlet to a catheter, a cavity divided by a flexible diaphragm to define a lower section and an upper section, means establishing fluid communication between said two sections, with said lower section in fluid communication with said inlet and with said upper section in fluid communication with said outlet, and means for adjusting the flow rate to said outlet from said upper section, whereby said flow regulator is set to a predetermined rate.

The invention and advantages of the invention will become more apparent from the following description taken in conjunction with the accompanying drawings wherein:

Fig. 1 is a schematic representation of the adjustable flow regulator according to this invention when used in conjunction with a pressure actuated drug delivery system; and

Fig. 2 is a section view of the flow regulator as illustrated in Fig. 1.

The implantable drug delivery system of the present invention is illustrated schematically in Fig. 1. It comprises an infusion pump 10 with a housing 12 divided into a drug chamber 16 and a propellant chamber 18 by means of a bellows or diaphragm 20. The infusion pump is implanted under the skin and the drug chamber may be refilled hypodermically utilizing a penetrable resilient fill septum 24. The chamber 18 contains "Freon" having a vapor pressure such that, under conditions of normal body temperature, creates a pressure upon the bellows 20 to force a drug contained in the chamber 16 out through the discharge opening 26, through a filter 30, to an adjustable flow rate regulator 28. The regulator incorporates a capillary type restrictor 38.

Referring to Fig. 2, the flow regulator 28 comprises a body formed by a top member 40 and a bottom member 42. The upper portion of the bottom member 42 and the lower portion of the top member 40 form an interior cavity and have mating surfaces at their peripheries. The mating peripheral surfaces of the top member 40 and the bottom member 42 are assembled and fastened together by any convenient means such as screws, (not illustrated) welding or the like. A resilient diaphragm 44 is welded to an annular flange 41 ex-

tending from the top member 40. The diaphragm is composed of a flexible but impervious material, such as titanium and is disposed in the cavity which the diaphragm divides into a lower section 46 and an upper section 48. The bottom member 42 has an inlet 50 which communicates with section 46. An outlet 52 communicates with section 48 and connects the regulator to the catheter 34.

Fluid from the drug chamber 16 flows through inlet 50 into the lower section 46. Fluid from the lower section 46 is delivered to the upper section 48 via duct 51 and opening 54 which are interconnected to the restrictor 38 via opening 56 and duct 53. By this technique then, fluid is delivered unrestricted to section 46 and then through the restrictor 38 to section 48. Thus, the restrictor 38 communicates directly across the diaphragm 44.

The outlet 52 is welded to an adjustable fitting 58 within top member 40. An O-ring 59 provides a seal in a recess of the fitting. The inner surface of the adjustable fitting engages a sealed movable annular plate 60. The plate 60 has a flexible metallic seal 64 welded at its periphery in a narrow recess in the top member 40 and has an O-ring valve 62 near its center. As can be appreciated then, adjustment of the fitting 58, produces deflection in the plate 60 and O-ring valve 62. Adjustment is by means of an internal Castle nut 66. By rotation of the Castle nut 66, which bears on a flange 68 of the upper adjustable fitting 58, a downward pressure is exerted on plate 60 and the O-ring valve 62 is urged towards the diaphragm 44. When the O-ring valve contacts the diaphragm the outlet 52 is thereby effectively sealed off. Adjustment from that sealed position is a function of movement of the Castle nut 66 so that a clearance exists between the O-ring valve and the surface of the diaphragm. By this technique, effective attenuation of the flow from section 48 to the outlet 52 can be established and maintained automatically by the varying forces on the diaphragm 44 due to changes in body temperature and atmospheric pressure.

This technique also provides for adjustment during manufacture to insure that the device is properly calibrated. Without such adjustment, the operation of the device would be a function of manufacturing tolerances which provide an inadequate basis by which to insure a predetermined regulated flow given the low volume flow rates.

In operation, medication from the drug chamber 16 is forced through the flow line 26 by the constant pressure exerted by the material in the chamber 18. The medication passing through the filter 30 is them delivered to the compensator through inlet 50. Medication flows into lower section 46 and via opening 54 into the restrictor 38. Then, it is delivered to the upper section 48 and through the outlet 52 into the catheter 34. Given the fact that there is fluid in both sections 46 and 48, opposing forces on the diaphragm generally null the system so that the diaphragm tends to remain stationery.

If, however, there is a change in these forces, for example, as a result of a decrease in flow through the catheter 34 because of a higher atmospheric pressure, then the diaphragm 44 will be deflected downward, due to a build up of pressure in section 48, automatically opening valve 62 increasing flow. If, on the other hand, the pressure in section 48 is reduced by a lowering a atmospheric pressure such as at a higher altitude, the diaphragm will be deflected upward toward O-ring valve 62 automatically closing the valve and reducing flow. Thus, the position of the diaphragm, which is controlled by the pressure differential between sections 46 and 48, effectively maintains a constant or near constant flow rate through outlet 52 to catheter 34.

Given the fact that movement of the diaphragm 44 to establish a flow rate from a fully seated no flow rate condition to the desired dosage level is very small, as discussed herein adjustability of the system is required. Thus, by using the Castle nut 66 and the adjustable diaphragm feature of movable plate 60 the initial distance between the O-ring 62 valve and the diaphragm 44 can be adjusted and set to give proper flow rate. This is a considered to be a significant improvement over prior art systems which do not allow for such adjustability.

It is apparent that modification and variations of this invention may be made without departing from the essential scope thereof.

Claims

1. A flow regulator 28 for use in an implantable drug delivery system, said regulator comprising a body 40, 42 having an internal cavity divided by a movable diaphragm 44 to define a lower section 46 and an upper section 48, an inlet 50 for receiving fluid from a pressure actuated drug delivery device 10 in said system and in fluid communication with said lower section, an outlet 52 in fluid communication with said upper section, a duct means 38 for establishing fluid communication between said lower and upper sections, and a means 66 for adjusting the flow rate to said outlet from said second section to a set, predetermined level.

2. A flow regulator as claimed in claim 1 wherein said outlet 52 is mounted in said body and is movable thereto, and said adjusting means 66 moves said outlet with respect to said diaphragm 44.

3. A flow regulator as claimed in claim 2 further

characterized by an adjustable fitting 58 sealed within said body 40 and having a flange 68, said outlet 52 connected to said adjustable fitting, a movable plate 60 coupled to said adjustable fitting and flexibly sealed at the periphery to said body allowing only normal movement in relation to said diaphragm 44, said plate including an O-ring valve 62 engageable with said diaphragm, and wherein said adjusting means comprises an adjusting nut 66 mounted in said body and contacting said flange 68 on said adjustable fitting, whereby movement of said nut positions said fitting and said O-ring valve relative to said diaphragm.

4. A flow regulator as claimed in claim 1, 2 or 3 wherein said diaphragm 44 is made of a resilient material mounted in said body 40, and said diaphragm is movable in response to a pressure differential between said section 46 and said section 48.

5. A flow regulator as claimed in claim 3 further comprising a flexible metallic seal 64 mounted to the periphery of said movable plate 60 and to said body 40, said seal movable in response to movement of said adjusting nut to maintain a seal in said section 48.

6. A flow regulator as claimed in any preceding claim, wherein said regulator body comprises a bottom member 42 having said inlet 50 and a recessed portion defining said lower section 46, and a top member 40 having said outlet 52 and said duct means 38 for providing fluid communication contained therein, and means to join said body members together in a sealed manner.

7. A flow regulator as claimed in claim 6, wherein said top member 40 includes an annular flange 41 with diaphragm 44 mounted on said flange.

8. An implantable drug delivery system including a flow regulator as claimed in any preceding claim.

9. An implantable drug delivery system according to claim 8, said pressure actuated drug delivery device 10 comprising a housing 12, a movable bellows dividing said housing into a first chamber 16 containing a drug to be dispensed and a second chamber 18 containing a material exerting pressure on said bellows and means 24 for providing access to said first chamber for refilling it with a drug, said first chamber being in fluid communication with said inlet 50.

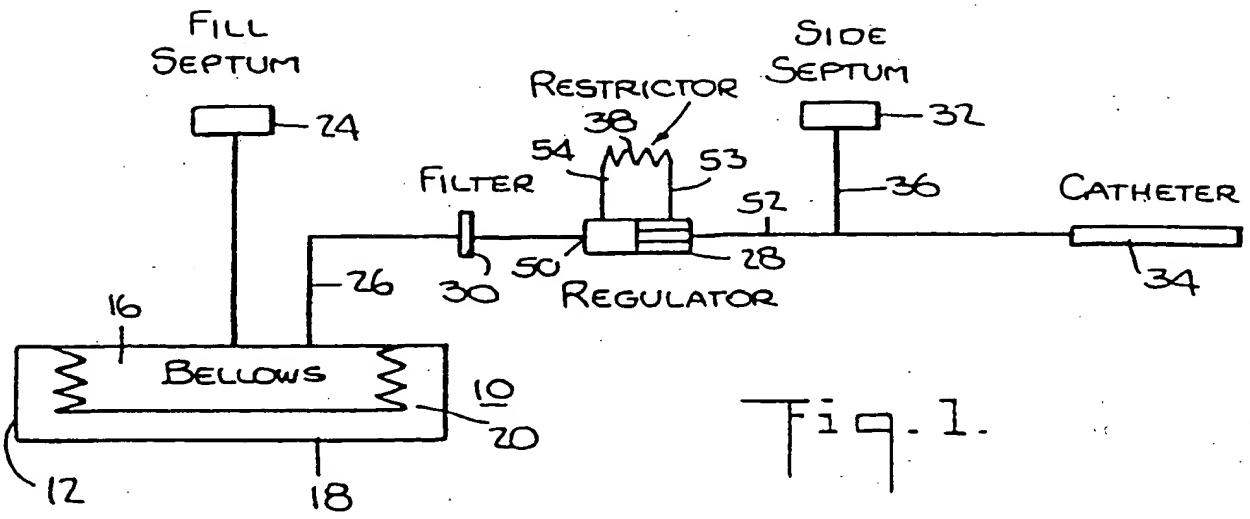

FILL SEPTUM
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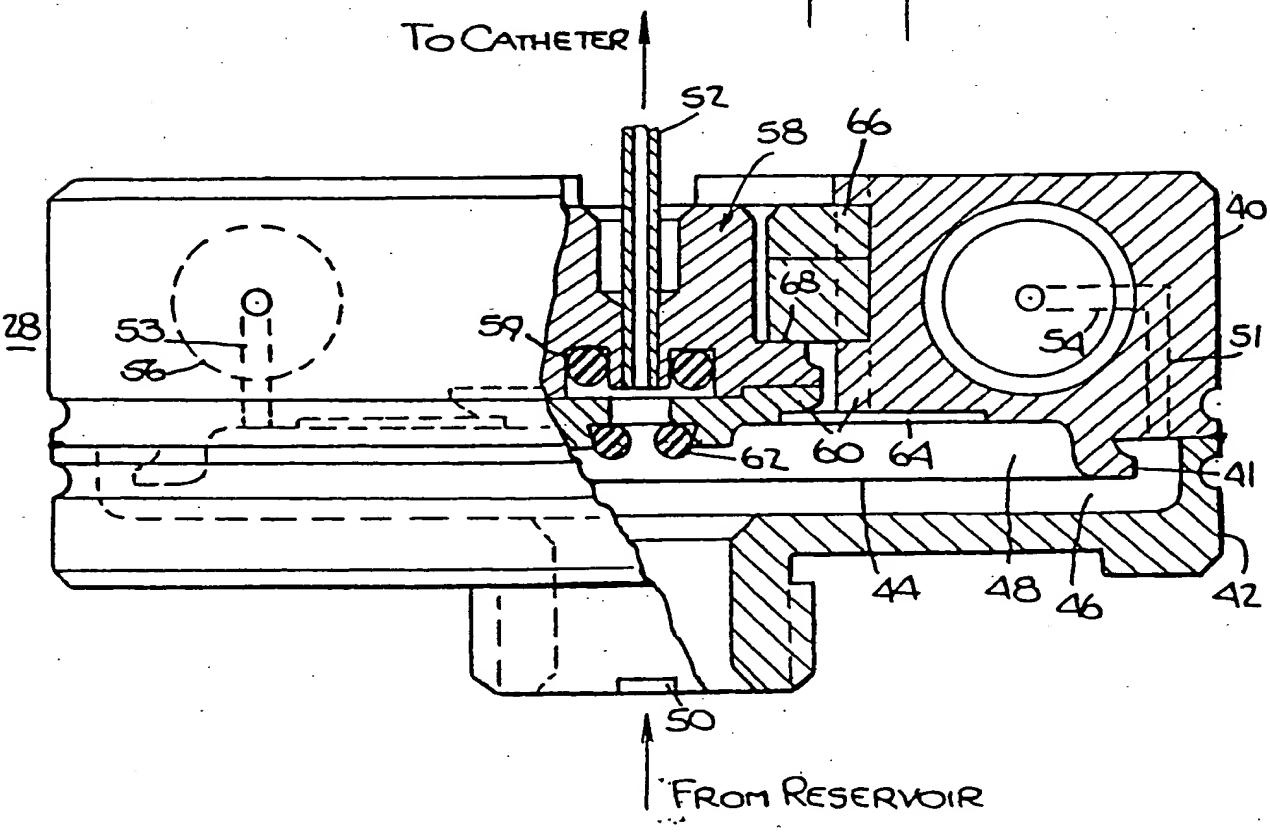
Fig. 1.

Fig. 2.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EUROPEAN SEARCH REPORT

Application Number

EP 90 30 7717

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y,D	WO-A-8 002 377 (UNIVERSITY OF MINNESOTA) * Abstract; page 4, line 33 - page 5, line 13; figure 1 *	1-4,8,9	A 61 M 5/168 G 05 D 7/01
Y	FR-A-1 299 719 (ANDRE CITROEN S.A.) * Page 1, column 2, lines 4-22; figures 1,3 *	1-4,8,9	
A	US-A-4 241 757 (BRON) * Column 3, line 33 - column 4, line 15; figure 2 *	1,2,4	
A,D	US-A-3 731 681 (BLACKSHEAR et al.)		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 M
G 05 D
F 16 J

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	24 October 90	CLARKSON P.M.

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
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E: earlier patent document, but published on, or after the filing date
D: document cited in the application
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